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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application N . | Applicant(s) |
| | 09/943,158 | BAILEY ET AL. |
| Examiner | Art Unit | |
| Taylor Victor Oh | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 March 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-69 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-69 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

The Status of claims :

Claims 1-69 are pending.

Claims 1-69 have been rejected.

Specification

The disclosure is objected to because of the following informalities: on pages 5 and 14, lines 21 and 21, a phrase “red currents” is written..

Appropriate spelling correction is required.

Claim Objections

Claims 20 and 44 are objected to because of the following informalities: a phrase “red currents” is written. Appropriate spelling correction is required.

Claim Rejections - 35 USC § 112

Claims 1, 14, 24, 36, 39, 48, 54, and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant material , such as blueberries, bilberries, blackberries, strawberries, red-currants, black-currants, cranberries, and etc. does not reasonably provide enablement for all the well-known plants in the world. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the plant

plant materials unrelated to the invention commensurate in scope with these claims.

Therefore, an appropriate correction is required.

The specification, while being enabling for a filter aid, such as diatomaceous earth or cellulose, and etc. does not reasonably provide enablement for all the filter aids known in the world. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the filter aids unrelated to the invention commensurate in scope with these claims. Therefore, an appropriate correction is required.

The specification, while being enabling for an excipient, such as preservatives, carriers, buffering agents, thickening agents, suspending agents, stabilizing agents, wetting agents, emulsifying agents, coloring agents, and flavoring agents, and etc. does not reasonably provide enablement for all the excipients known in the world. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the excipients unrelated to the invention commensurate in scope with these claims. Therefore, an appropriate correction is required.

The specification, while being enabling for a reversed phase resin, such as polymethacrylate, styrene, divinylbenzene, trivinylbenzene, alkylvinylbenzene, acrylvinylbenzene, and methyl methacrylate, and etc. does not reasonably provide enablement for all the reversed phase resins in the world. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the reversed phase resins unrelated to the invention

commensurate in scope with these claims. Therefore, an appropriate correction is required.

Claims 9, 25, 29, 33, 49, 55, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A phrase " an extraction solvent" is written. However, this is vague and indefinite as to what " the extraction solvent" can be used in the process. Therefore, an appropriate correction is required.

A group of words "preservatives, carriers, buffering agents, thickening agents, suspending agents, stabilizing agents, wetting agents, emulsifying agents, coloring agents, and flavoring agents" and "plant sterols, flavonoid glycosides, fatty acids, triglycerides, and other impurities " are written. However, this is vague and indefinite. Each of them are unspecified in the claims and the specification. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 102

2113 Product-by-Process Claims
PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATION OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." In re Thorpe, 77 F.2d 695,698,227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive prereacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Levy et al (U.S. 5,780,060).

Levy et al discloses a dry aqueous-alcoholic blueberry extract which contains anthocyanosides in an amount corresponding to 15 % of anthocyanidines (see col. 13, lines 61-63). This is identical with the claims.

Claims 53-54, 56-58, 60 and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Gabetta et al (U.S. 5,200,186).

Gabetta et al discloses a commercial Vaccinium myrtillus extract contains 35 % of anthocyanosides (see col. 3 ,lines 45-46) , which can be used in a therapy in the pathology of capillaries and in the ophthalmology (see coil. 1 ,lines 12-15). Besides anthocyanosides, it may have mineral salts, common organic acids, and etc. (see col. 1 ,lines 27-30). This is identical with the claims.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabetta et al (U.S. 5,200,186) in view of Langston (U.S. 4,500,556) and S.O.R.I.(GB 1,235,379).

Gabetta et al discloses a commercial Vaccinium myrtillus extract contains 35 % of anthocyanosides (see col. 3 ,lines 45-46) , which can be used in a therapy in the pathology of capillaries and in the ophthalmology (see coil. 1 ,lines 12-15). Besides anthocyanosides and aglycones (see col. 1 ,lines 16-18), it may have mineral salts, common organic acids, and etc. (see col. 1 ,lines 27-30).

Furthermore, Gabetta et al teaches a method of preparing a high concentration of anthocyanosides from the fruits of Vaccinium myrtillus, Ribes nigrum, Vitis vinifera, Sambucus, and other plants (see col. 1, 11-12) in the following steps of :

- a. extracting Vaccinium myrtillus fruits with 50 % aqueous methanol;
- b. adding sodium bisulfite to the solution;

- c. charging the solution to a non-polar polystyrenic resin;
- d. washing the column with 8 liter of water, thereby eluting anthocyanosides;
- e. concentrating the eluted aqueous solution under vacuum;
- f. acidifying the aqueous solution with 1% hydrochloric acid solution;
- g. extracting the aqueous solution with butanol;
- h. washing the resultant solution with HCl solution; and
- i. precipitating the solid and being dried under vacuum (see col. 3, example 1).

As a result of the process, the extract of anthocyanosides contains the following composition (%): delphinidin galactoside 13.20, delphinidin glucoside 15.00, delphinidin arabinoside 9.06, cyanidin galactoside 7.25, cyanidin glucoside 9.06, cyanidin arabinoside 4.41, petunidin galactoside 3.88, petunidin glucoside 9.07, petunidin arabinoside 1.94, peonidin galactoside 0.65, peonidin glucoside 3.45, peonidin arabinoside 0.24, malvidin galactoside 3.02, peonidin glucoside 9.06, peonidin arabinoside 0.95 (see col. 3 ,lines 30-40).

Furthermore, during the extracting step, a polar organic solvent immiscible with water is used(see col. 3 ,lines 30-40).

The instant invention ,however, differs from the Gabetta et al reference in that pectinase is present in the extract; the brominated polystyrene resin is employed ; the filtering step takes place before adding a source of bisulfite ions ; the composition is

isolated through an anion exchange column; and a filter aid is added to the crude extract.

Langston teaches a process of anthocyanin colorant from grape pomace in the following procedure:

- a. contacting grape pomace with an aqueous extraction solvent containing HSO_3^- ions to extract an anthocyanin-bisulfite ion adduct;
- b. removing the aqueous extractantion solvent and undissolved solids from the grape pomace by filtration;
- c. contacting the aqueous extraction solvent with a non-ionic adsorbent to adsorb the anthocyanin-bisulfite pigment complex;
- d. washing the adsorbent to remove soluble sugar, organic acid and other water soluble non-pigmented material; and
- e. eluting the anthocyanin from the adsorbent with an acidified organic solvent (see col. 2 ,lines 6-27).

In addition, during the process, the extract solution is filtered to remove undissolved solids in any convenient manner (see col. 3 ,lines 14-16).

Furthermore, S.O.R.I. discloses a process for extracting anthocyanines from certain berries and fruits by using extraction solvents, such as water ,methanol, ethanol or butanol or any mixture thereof (see page 2 , lines 32-35). During the process of

yielding juice, pectinase can be added to the crushed fruits (see page 1, 39-45). Furthermore, the composition of the unpurified extract may contain 27 to 30 % of anthocyanins, traces of aglycone, monosaccharides, traces of pectins, and organic ions (see page 2 ,lines 55-68). The pre-concentrated liquid and juice may be treated by means of ion exchange resins to form anthocyanin cations. These cations can be selectively fixed by anionic resins. The recovery of anthocyanins happens in the strong acidic medium, such as hydrochloric acid (see page 2 ,lines 75-81).

Concerning the use of the brominated polystyrene resin ,in the process, Gabetta et al does indicate the broad use of the non-polar polystyrenic resin to which the brominated polystyrene resin may be belonged. Furthermore, there is little difference between their respective functionalities during the purification processes. Furthermore, this does not have any patentable weight over the prior art reference. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to use as an alternative in order to enhance the process .

Regarding the filtering step prior to adding a source of bisulfite ions, it has been held that merely reversing the order of steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. Ex parte Rubin, 128 U.S.P.Q. 440 (P.O.B.A. 1959). Cohn v. Comr .Patents , 251 F. supp. 437, 148 U.S.P.Q. 486 (D.C. 1966).

With respect to the use of the filter aid, this is directly related to the optimization of filtration. Furthermore, this does not have any patentable weight over the prior art reference. Therefore, it would have been obvious to the skillful artisan in the art to have

motivated to optimize the filtration process with the filter aid in order to enhance the process .

All three references have commonly shared the process of preparing the high concentration of anthocyanosides from the fruit by means of extraction and ion exchange resins. Gabetta et al does teach the general method of preparing the high concentration of anthocyanosides from the various fruits by extracting the fruits containing anthocyanines in the presence of the polar organic solvent by means of the non-polar polystyrenic resin. Langston does indicate that after filtering, the extract solution is contacted with the non-ionic adsorbent. And S.O.R.I. does point out that the pre-concentrated liquid and juice may be purified by means of ion exchange resins to form anthocyanin cations, which, in turn, these cations can be fixed by anionic resins in order to obtain anthocyanins. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to incorporate Langston's filtration step prior to contacting ion exchange resins in the Gabetta et al process ,along with the use of S.O.R.I.'s anionic resins, thereby enhancing the purification process of anthocyanins. This is because the skilled artisan in the art would expect the combined processes to increase the purity of the desired compound as well as to have a similar success as shown in the S.O.R.I. process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2742 for regular communications and 703-305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

AR
April 2, 2003

Alan L. Rotman
ALAN L. ROTMAN
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